K130648

SECTION 5.   510(K) SUMMARY

5. 510(K) SUMMARY

510(k) SUMMARY
(per 21 CFR §807.92)

FORUM Glaucoma Workplace   JUL 2 3 2013

GENERAL INFORMATION

Manufacturer: Carl Zeiss Meditec AG
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Date prepared: July 12, 2013

Device   System, Image Management, Ophthalmic

Classification: 21 CFR 892.2050
                         21 CFR 886.1605

Device Class: II

Product Code: NFJ
                         HPT

Common Name: Picture Archiving and Communications System

Trade/Proprietary Name: FORUM Glaucoma Workplace

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PREDICATE DEVICES:

Company: Carl Zeiss Meditec AG
Device: FORUM
                   (K122938)

Company: Carl Zeiss Meditec, Inc.
Device: Guided Progression Analysis (GPA) for the Humphrey
                   Field Analyzer II and II-*i* series
                   (K093213)

INTENDED USE

FORUM Glaucoma Workplace is a FORUM software application intended for the management, display, and analysis of visual field data.

INDICATIONS FOR USE

FORUM Glaucoma Workplace is a FORUM software application intended for the management, display, and analysis of visual field data. The FORUM Glaucoma Workplace is indicated as an aid to the detection, measurement, and management of progression of visual field loss.

DEVICE DESCRIPTION

FORUM Glaucoma Workplace is a FORUM software application that provides a means to review and analyze data from various visual field examinations to identify statistically significant and progressive visual field loss. FORUM Glaucoma Workplace utilizes Humphrey® Field Analyzer (HFA) algorithms and databases including STATPAC and Guided Progression Analysis (GPA) to process visual field data and generate visual field reports. GPA compares visual field test results of follow-up tests to an established baseline over time and determines if there is statistically significant change.

The following are the main functionalities of FORUM Glaucoma Workplace:

- Data retrieval and report storage
- Managing, analyzing and displaying visual field exams
- Creation of visual field reports

FORUM Glaucoma Workplace retrieves HFA visual field test data from the FORUM Archive, uses the HFA algorithms and databases to process the visual field raw data, then generates and displays visual field reports. The reports generated by FORUM Glaucoma Workplace are stored as DICOM Encapsulated PDFs in the FORUM Archive.

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FORUM Glaucoma Workplace displays interactive screens and the generated visual field reports. These reports include those previously offered by the HFA II and HFA II –*i*: Single Field Analysis; Overview; Guided Progression Analysis (GPA) Summary, Full GPA, GPA Last Three Follow-up and Single Field Analysis (SFA) GPA.

After launching FORUM Glaucoma Workplace from the FORUM application, two tabs are presented: Overview and GPA.

Overview Tab
FORUM Glaucoma Workplace creates and displays visual field reports for visual field tests provided the visual field examination results have been stored in FORUM. These reports include the Overview and Single Field Analysis report which previously could only be created on the Humphrey Field Analyzer II or II-*i* instrument. The Overview report contains the data of all existing tests selected. The Single Field Analysis report contains data from a single central threshold test. The reports generated by FORUM Glaucoma Workplace contain the same information as previously provided on the HFA instrument and utilize the same algorithms and databases.

Interactive Features
The main interactive functionalities available in the Overview tab are as follows:

Right-clicking on an exam
Right-clicking on an exam displayed in the Overview presents a context menu offering the option to "Show SFA Report" or "Enter IOP".

Double-clicking on an exam
Double-clicking on an exam displayed in the Overview presents a Single Field Analysis (SFA) report of the individual exam.

GPA Tab
FORUM Glaucoma Workplace contains the same GPA algorithms and databases as offered in the Humphrey® Field Analyzer II and II-*i* and allows GPA to be performed on a computer running FORUM independent of and apart from the visual field instrument itself. Within the GPA tab, GPA information is provided on interactive screens.

The GPA makes it possible to undertake progression analyses of ongoing exam data. The results of the Progression Analysis and the exams they are based on are shown under the GPA tab. All of the patient's suitable data that are stored in FORUM are available for analysis. Each analysis can be saved as a report in PDF form.

GPA analysis can be performed for any patient who has at least two baseline visual field tests. These tests must have been performed with the Full Threshold, Swedish Interactive Threshold

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Algorithm (SITA) Standard, or SITA Fast test strategies. Also, at least one follow-up visual field test must have been performed using either the SITA Standard or SITA Fast test strategy.

FORUM Glaucoma Workplace provides GPA that can compare the established baseline with up to 98 follow-up tests and determine whether there is statistically significant change. GPA highlights any changes from the baseline that represent larger than the expected clinical variability. In addition, it provides messages such as "Possible Progression" or "Likely Progression" when the changes show consistent and statistically significant loss. Progression is a statistically significant change that is also clinically repeatable and consistent. A statistically significant change from baseline in the same three or more points in two consecutive follow-up tests will result in a message on the report indicating "Possible Progression". The same scenario but in three consecutive follow-up tests will result in a message on the report indicating "Likely Progression".

From the GPA tab, users can create four types of GPA reports: Full GPA, GPA Summary, GPA Last Three Follow-up and Single Field Analysis (SFA) GPA. A Single Field Analysis report can also be created within the GPA tab. The same elements are utilized as with GPA on the Humphrey Field Analyzer II and II-*i*, however, within FORUM Glaucoma Workplace, some of the symbols and text on the screens and printouts are in color rather than in black and white.

FORUM Glaucoma Workplace allows the user to interact with the available data. When viewing the GPA on the screen, the user can hold the mouse pointer over a particular area and a small tooltip will appear with details regarding the particular test. The tooltip provides information such as the test date, test pattern and strategy.

Representation of the Data and Results

Visual Field Plots:

Threshold Plot
The threshold plot presents the measurement results in numerical (decibel) form.

Graytone Plot
The graytone representation of the patient's visual field provides an immediate idea of the size and depth of any field defects present. Each variation of the pattern corresponds to a 5 dB change in sensitivity.

Total Deviation Plot
The Total Deviation Plots reflect the total deviation of the threshold values at every test point.

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Pattern Deviation Plot
Pattern Deviation is represented in the same format as the Total Deviation Plot, with adjusted STATPAC analysis of the test results.

Reliability Indices
The following Reliability Indices are indices used in the visual field reports:
- Fixation Loss (FL)
- False Negative errors (FN)
- False Positive errors (FP)

The fixation loss is presented as a fraction of the total fixation loss over the total of the stimuli present in the blind spot. For the Swedish Interactive Threshold Algorithm (SITA) Standard and SITA Fast testing strategies, the false negative and false positive errors are presented in percent. For Full Threshold and FastPac tests, false positive errors, false negative errors, and fixation losses are all printed as a ratio. The false positive and false negative results will appear as a fraction (i.e., total number of false positive errors divided by the total number of trials).

Global Indices
The following Global Indices are presented in the visual field reports:
- MD – Mean Deviation
- PSD – Pattern Standard Deviation
- VFI – Visual Field Index

MD and PSD indices are provided in numerical values in decibels (dB). The Mean Deviation is the average elevation or depression of the patient's overall field compared to the normal reference field. The Pattern Standard Deviation is a measure of the degree to which the shape of the patient's measured field departs from the normal, age adjusted reference field. The Visual Field Index is a measure of the patient's overall visual function as compared to an age adjusted normal population. The VFI is presented as a percentage.

The last index, the Glaucoma Hemifield Test (GHT), is also presented on the visual field report for tests completed using the 24-2 or 30-2 test pattern. The Glaucoma Hemifield Test (GHT) evaluates five zones in the superior field and compares these zones to their mirrored zones in the inferior field. The GHT evaluates the severity of disturbed points in each zone pair, relative to its normative database, and shows a message such as: Within Normal Limits; Outside Normal Limits or Borderline.

GPA Plots:

Deviation from Baseline Plot
The Deviation from Baseline Plot is a graph presented in numerical values measured in decibels

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(dB) similar to the Total and Pattern Deviation Plots. This plot compares the pattern deviation values of the follow-up test to the pattern deviation values of the average of the two baseline tests.

Progression Analysis Probability Plot
The Progression Analysis Probability Plot gives the statistical significance of the decibel changes shown in the Deviation from Baseline Plot. It compares the changes between the Baseline and Follow-up exams to the inter-test variability typical of stable glaucoma patients and then shows a plot of point locations which have statistically changed.

Global Indices
The same global indices available on other visual field results (Mean Deviation (MD), Pattern Standard Deviation (PSD), and Visual Field Index (VFI) are presented on the GPA results.

GPA Alert
The GPA Alert allows the user to recognize possible deterioration in consecutive tests. The alerts that are displayed include "Possible Progression" and "Likely Progression". When there are three or more points that show statistically significant deterioration in at least two consecutive tests, the progression analysis indicates "Possible Progression". In the same scenario but with at least three consecutive tests, then the progression analysis alert indicates "Likely Progression".

Visual Field Index
The Visual Field Index is a measure of the patient's overall visual function as compared to an age adjusted normal population. The VFI is presented as a percentage.

VFI Plot
The VFI Plot is a trend plot that shows a linear regression analysis of the VFI for all exams included in the analysis over time. The VFI values for all exams are graphically presented as a function of the patient's age. The open square symbols represent VFI values from the Full Threshold exams whereas the filled square symbols represent VFI values from SITA exams.

VFI Bar
The VFI Bar is a histogram that provides a graphical representation of the patient's current VFI value. A two to five year projection of the VFI regression line is also shown.
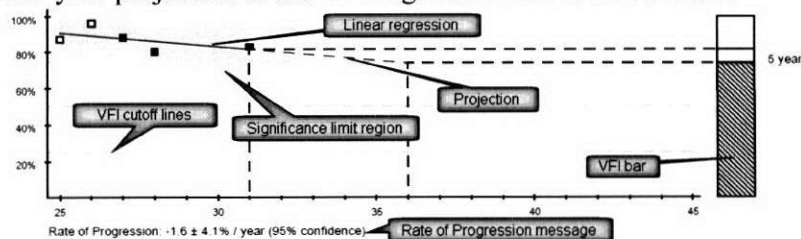
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The VFI plot contains the following symbols:

Test Strategy: Full Threshold	Test Strategy: SITA Standard or SITA Fast	Meaning
⬭	⬭	Test defined as baseline for the Progression Analysis (Baseline exam). The test results are graphically displayed above the VFI plot.
⬭	⬭	Test defined as Baseline for the Progression Analysis (Baseline exam). When the results of the earliest selected Baseline test [independent of the user's input (automatically or manually selected)] shows a significant learning effect, the test appears in red in the VFI Plot in the monitor display. The red shading indicates that a learning effect has occurred. . If a test is designated to be the first baseline test, but its VFI value is so low that it falls below the p <2.5% level of a linear regression analysis of subsequent tests not including the test in question, then the software will flag the test with a red color coding. This test is therefore not suitable as a Baseline test; another exam should be used as the Baseline test.
☐	■	Follow up test taken into consideration for the Progression Analysis.
☐	■	The blue shading indicates that this test is currently highlighted. This test's results are graphically displayed below the VFI Plot in the evaluation area.
☐	☐	This test is not taken into consideration for the Progression Analysis for the following reason: – It has been deselected by the user.
☐	☐	This test is not taken into consideration for the Progression Analysis for the following reason (automatically excluded by the software): – It is older than the data from the newest Baseline test. – 100 tests have already been taken into consideration. – In the event that the Baseline tests are SITA Standard or SITA Fast, Full Threshold tests are not taken into consideration.

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Test Strategy: Full Threshold	Test Strategy: SITA Standard or SITA Fast	Meaning
▯		This test contains more than 33% false positive data and is therefore not taken into consideration for the analysis.
	▯	This test contains more than 15% false positive errors and is therefore not taken into consideration for the analysis.

The VFI plot offers the following color coding:

Indices	Deviation Probability	Color for Numbers
VFI	-	Dark Blue
Fovea Threshold (not measured)	-	Dark Blue ("Off" entry)
Fovea Threshold (when measured) MD, PSD, SF, CPSD	Not Significant	Green
	P < 10%	Green
	P < 5%	Orange
	P < 2%	Orange
	P < 1%	Red
	P < 0.5%	Red

The analysis used to evaluate the baseline tests in FORUM Glaucoma Workplace is the same as previously available using Guided Progression Analysis on the Humphrey Field Analyzer II and Humphrey Field Analyzer II-*i* series instruments.

As with the HFA II and II-*i*, the algorithms within GPA evaluate the selected baselines for a learning effect. The FORUM Glaucoma Workplace automatically applies a red color coding to all selected baselines showing a significant learning effect. This action is independent from automatic selection or the user manually selecting the baselines. If a test is designated to be the first Baseline test, but its VFI value is so low that it falls below the $p<2.5\%$ level of a linear regression analysis of the subsequent tests (not including the test in question), then the software will flag the test with a red color coding. The color coding is provided to draw the user's attention to the fact that the test selected indicates a learning effect and may not be an appropriate test to include as one of the two Baseline tests. A test that indicates a learning effect is considered a 'non representative baseline test'.

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Interactive Features

The main interactive functionalities available in the GPA tab are as follows:

Selecting the testing strategy:

Selecting the SITA Standard testing strategy takes into account all tests of the SITA Standard and Full Threshold strategies.

Selecting the SITA Fast testing strategy takes into account all tests of the SITA Fast and Full Threshold strategies.

Selecting an exam as Baseline test:

The exam(s) to be used as the Baseline test can be changed.

The Baseline is always comprised of two exams. Both Baseline exams must have been administered with the same testing strategy (Full Threshold or SITA Standard or SITA Fast).

Excluding tests from the GPA (deselect):

Test(s) can be excluded from GPA, provided it is not defined as a Baseline Test.

Saving GPA as a report:

The GPA can be saved in various GPA report formats: GPA Summary, Full GPA, SFA GPA and GPA Last Three Follow-up.

Right-clicking on an exam:

When the GPA analysis is displayed on the interactive screen, users can right-click on a test symbol to be presented with a context menu offering various options regarding the particular test chosen:

Follow-up Test	Deselected Follow-up Test	Baseline Test	Automatically Excluded Test
Deselect	Select as Follow-up		
Set as Baseline	Set as Baseline	Set as Baseline	
Show SFA report	Show SFA report	Show SFA report	Show SFA report
Enter IOP	Enter IOP	Enter IOP	Enter IOP

By choosing one of the options, the test may either be included or excluded in the GPA, used as a Baseline or Follow-up, etc.

Changing baselines and deselecting exams are persistent across users. The last edit entered is the one that will be carried over to the next session independent of the user who entered the edit.

Show exam status:

When the mouse pointer is held over an icon representing an exam displayed in the GPA, information regarding the exam such as 'Follow-up exam', 'Baseline exam', 'Excluded exam' and testing information (test date, test strategy, etc.) is provided.

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Double-clicking on an exam:
Double-clicking on the icon representing an exam displayed in the GPA presents a Single Field
Analysis (SFA) report of the individual exam.

Show/Hide all deselected exams:
Within the VFI plot, tests that have been "deselected" from the GPA analysis can be 'hidden'
from view. Once 'hidden', the deselected exams can be 'shown' again by toggling the interactive
button. The state of the "Show/Hide all deselected exams" button is not persistent, i.e., every
time a user accesses the GPA screen, the deselected exams are always shown.

When viewing the VFI plot on screen, the user has options to view more data by selecting a
given function button and rolling the mouse wheel as indicated in the following table:

Button	Function
🔍	Enlarge display of VFI Plot The plot can be zoomed in or out when the mouse pointer is on it by scrolling the mouse wheel.
🔍	Reduce VFI Plot display.
🔍	Show VFI Plot in original size.
▷	Scroll through tests. → The results of the Follow-up tests are shown consecutively below the VFI Plot. → Another click on the button stops scrolling.
⊏〇⊐	Setting the scrolling speed for the tests.

By selecting the scroll button, ▷, the software presents the results of the Follow-up tests
(depicted by circles in the VFI plot) in a continuous loop. In situations where multiple users use
a single device, changes entered such as changing the baseline test or manual de-selection of a
test (and the resulting color-coding), persist across users.

Technological Characteristics
FORUM Glaucoma Workplace is connected to FORUM via an internal interface; it consists of a
server and client that integrate into an existing FORUM Archive and Viewer installation. Once
FORUM Glaucoma Workplace installed and licensed, the new functionality becomes available
in FORUM Viewer.

The server is installed on the FORUM server. The data access components are located on the
server. The server installation enables FORUM Glaucoma Workplace to retrieve HFA exam
data stored in the FORUM Archive. It also contains the algorithms and databases to process the
data and create visual field reports.

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The client is installed on the FORUM Viewer. The display components are located on the client. The client installation enables FORUM Glaucoma Workplace to display visual field results and the user interaction information.

The reports are displayed on a computer monitor with interactive screens using the FORUM Viewer. The created reports are stored as DICOM Encapsulated PDFs in the FORUM Archive.

SUBSTANTIAL EQUIVALENCE

The FORUM Glaucoma Workplace is substantially equivalent to the predicate devices with regard to the indications for use statement and is functionally equivalent to the predicate devices.

FORUM Glaucoma Workplace and the predicate device, FORUM (K122938), present reports which contain perimetry results and both devices transfer and accept data. Both devices utilize client-server systems.

FORUM Glaucoma Workplace and the predicate device, Guided Progression Analysis (GPA) for the Humphrey Field Analyzer II and II-*i* series (K093213), and FORUM (K122938) are software devices. The primary software functionalities in the predicate devices including STATPAC and Guided Progression Analysis and their associated data plots (Threshold; Graytone; Total Deviation; Pattern Deviation; Deviation from Baseline; Progression Analysis Probability, VFI), global indices (Mean Deviation, Pattern Standard Deviation) and reliability indices (Fixation Losses; False Negative and False Positive errors) as well as the GPA alert, VFI Index and VFI Bar are implemented in FORUM Glaucoma Workplace.

FORUM Glaucoma Workplace and the predicate device, Guided Progression Analysis (GPA) for the Humphrey Field Analyzer II and II-*i* series (K903213), provide visual field analysis functionalities and use Guided Progression Analysis to evaluate a patient's test results over time to determine if there has been any statistically significant change since the baseline was established. If such change is determined, both devices inform the reviewer with a "GPA Alert". Both devices use data to create the GPA analysis and manage data in that the GPA analysis can be updated with regards to establishing new baselines and/or utilizing new exams for follow-up which in turn is utilized in the management of progression of visual field loss.

Differences:

FORUM Glaucoma Workplace allows the user to see the visual field reports (GPA, Single Field Analysis, Overview) on a computer monitor or in a printed format whereas reports generated on the predicate device, GPA for the Humphrey Field Analyzer II and II-*i*, could only be viewed in a printed format.

FORUM Glaucoma Workplace allows the user to interactively change the visual field tests included as a Baseline or Follow-up test when performing GPA and to see the result of the

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change immediately on the computer monitor whereas when the user changed the selected test(s) on the predicate device, GPA for the Humphrey Field Analyzer II and II-*i*, a new report would have to be printed in order to see the updated GPA.

FORUM Glaucoma Workplace retrieves the visual field data from the FORUM Archive whereas the predicate device retrieved visual field data from information stored on the Humphrey Field Analyzer instrument.

FORUM Glaucoma Workplace indicates the selected earliest Baseline test in red color if it shows a significant learning effect in the VFI Plot, whereas the predicate device, GPA for the Humphrey Field Analyzer II and II-*i*, displayed a message to the user that stated: *"First examination should not be used as Baseline due to marked learning effects."*

FORUM Glaucoma Workplace offers the visual field analyses previously available on the predicate device, GPA for the Humphrey Field Analyzer II and II-*i*, as a software within FORUM, whereas the predicate device, GPA for the Humphrey Field Analyzer II and II-*i*, offered the visual field analyses as software within the Humphrey Field Analyzer instrument.

FORUM Glaucoma Workplace creates the visual field reports whereas the predicate device, FORUM, presents a PDF of visual field reports stored in FORUM.

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Trade Name	**Proposed Device** FORUM Glaucoma Workplace	**Predicate Device** FORUM (K122938) including FORUM Archive FORUM Archive &Viewer FORUM ASSIST match	**Predicate Device** Guided Progression Analysis (GPA) for the Humphrey® Field Analyzer II and II-*i* series (K093213)
Manufacturer	Carl Zeiss Meditec AG	Carl Zeiss Meditec AG	Carl Zeiss Meditec Inc.
Device	System, Image Management, Ophthalmic	System, Image Management, Ophthalmic	Perimeter
Regulation Description	Picture archiving and communications system	Picture archiving and communications system	Perimeter
Regulation Medical Specialty	Radiology	Radiology	Ophthalmic Devices
Review Panel	Ophthalmic	Ophthalmic	Ophthalmic
Product Code	NFJ HPT	NFJ	HPT
Regulation Number	892.2050 886.1605	892.2050	886.1605
Device Class	II	II	II
Indications for Use	FORUM Glaucoma Workplace is a FORUM software application intended for the management, display, and analysis of visual field data. The FORUM Glaucoma Workplace is indicated as an aid to the detection, measurement, and management of progression of visual field loss.	FORUM is a software system intended for use in storage, management, processing, and display of patient, diagnostic, video and image data and measurement from computerized diagnostic instruments or documentation systems through networks. It is intended to work	The Carl Zeiss Meditec, Inc. Guided Progression Analysis is a software analysis module for the Humphrey® Field Analyzer II (HFA II) and Humphrey Field Analyzer II-*i* series (HFA II-*i*) that assists practitioners with the detection, measurement, and management of progression of

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Trade Name	Proposed Device FORUM Glaucoma Workplace	Predicate Device FORUM (K122938) including FORUM Archive FORUM Archive &Viewer FORUM ASSIST match	Predicate Device Guided Progression Analysis (GPA) for the Humphrey® Field Analyzer II and II-*i* series (K093213)
		with other FORUM applications. FORUM is intended for use in review of patient, diagnostic and image data and measurement by trained healthcare professionals.	visual field loss. It aids in assessing change over time, including change from baseline and rate of change. It is intended for use as a diagnostic device to aid in the detection and management of ocular diseases including, but not limited to, glaucoma.
Platform / Windows Operating System	Mac Lion (Client only) Windows 7,32 bit (Client only) Windows 7, 64 bit Windows Server 2003 Windows XP Windows Server 2008 R2	Windows XP, Windows Server 2003 (Server only) Windows 7 Windows Server 2008 R2 Mac Lion (Client only)	Embedded VxWorks Operating System

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Trade Name	Proposed Device FORUM Glaucoma Workplace	Predicate Device FORUM (K122938) including FORUM Archive FORUM Archive &Viewer FORUM ASSIST match	Predicate Device Guided Progression Analysis (GPA) for the Humphrey® Field Analyzer II and II-*i* series (K093213)
Perform Guided Progression Analysis (GPA)	Yes	No	Yes
Display GPA results: GPA Summary	Yes	Yes-presents PDF of report stored in FORUM	Yes
Display GPA results: GPA Last Three follow up	Yes	Yes-presents PDF of report stored in FORUM	Yes
Display GPA results: Full GPA	Yes	Yes-presents PDF of report stored in FORUM	Yes
Display GPA results: SFA GPA	Yes	Yes-presents PDF of report stored in FORUM	Yes

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Trade Name	Proposed Device FORUM Glaucoma Workplace	Predicate Device FORUM (K122938) including FORUM Archive FORUM Archive &Viewer FORUM ASSIST match	Predicate Device Guided Progression Analysis (GPA) for the Humphrey® Field Analyzer II and II-*i* series (K093213)
Display of Visual Field Information of a single exam: SFA (Single Field Analysis)	Yes	Yes-presents PDF of report stored in FORUM	Yes
Serial display of Visual Field Information from multiple exams: Overview	Yes	Yes-presents PDF of report stored in FORUM	Yes
STATPAC 2 algorithms and databases	Yes	No	Yes
STATPAC algorithms and databases for SWAP	Yes	No	Yes
STATPAC algorithms and databases for SITA	Yes	No	Yes
STATPAC algorithms and databases for SITA SWAP	Yes	No	Yes
Glaucoma Hemifield Test	Yes	No	Yes
Data Plots: Threshold; Graytone; Total Deviation; Pattern Deviation; Deviation from Baseline;	Yes	Yes – as presented in stored PDF reports	Yes

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Trade Name	Proposed Device FORUM Glaucoma Workplace	Predicate Device FORUM (K122938) including FORUM Archive FORUM Archive &Viewer FORUM ASSIST match	Predicate Device Guided Progression Analysis (GPA) for the Humphrey® Field Analyzer II and II-*i* series (K093213)
Progression Analysis Probability; VFI			
Global Indices: Mean deviation; Pattern Standard Deviation	Yes	Yes – as presented in stored PDF reports	Yes
Reliability Indices: Fixation Losses; False Positive errors; False Negative errors	Yes	Yes – as presented in stored PDF reports	Yes
Add comments	Yes	Yes	Yes
Storage of data	No	Yes	No
Management of data	Yes - management of progression of visual field loss.	Yes	Yes-management of progression of visual field loss.
Transfer of data	Yes	Yes	No
Acceptance of data	Yes	Yes	No

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PERFORMANCE DATA

Performance testing was conducted on FORUM Glaucoma Workplace and it was found to perform as intended. Each function and/or feature was tested by means of an appropriate test case or test specification. The verification testing demonstrates that the device performance complies with specifications and requirements identified for FORUM Glaucoma Workplace.

Verification and validation was conducted to ensure that the medical device meets the product and user requirements and to support a determination of substantial equivalence to the predicate devices.

The software verification activities were divided into three phases:

- Tests accompanying development (including code inspections)
- Module and integration test phase – stabilization phase
- System verification

As part of the verification testing, the visual field reports (Single Field Analysis, Overview, and Guided Progression Analysis) generated on the HFA II-*i* were compared to the reports generated by FORUM Glaucoma Workplace using the same test data to verify that the results contained in both reports were equivalent.

The client and server operating systems were also evaluated during verification. The results determined that FORUM Glaucoma Workplace is suitable for the same client operating systems for which the respective FORUM Archive & Viewer client version is released and that it is suitable under the following server operating systems:

- Windows XP (32 bit) with Service Pack 3
- Windows 7 (32 or 64 bit) with Service Pack 1
- Windows Server 2003 (32 bit) with Service Pack 2
- Windows Server 2008 (TS) R2 (64 bit) with Service Pack 1

Validation of clinical functionalities was completed by ophthalmologists in two countries using FORUM Glaucoma Workplace software as well as representative data (sample data that is representative of true clinical cases) installed on a computer. The validation participants executed test cases that simulated the use of the device in a clinical environment and completed questionnaires rating the various aspects of the software.

Verification and validation activities were successfully completed and prove that the product FORUM Glaucoma Workplace meets its requirements and performs as intended.

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SUMMARY

As described in this 510(k) Summary, all testing deemed necessary was conducted on FORUM Glaucoma Workplace to ensure that the device is as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 23, 2013

Carl Zeiss Meditec, Inc.
℅ Ms. Mandy Ambrecht
Staff Regulatory Affairs Specialist
5160 Hacienda Drive
Dublin, CA 94568

Re: K130648
Trade Name: FORUM® Glaucoma Workplace
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving and Communications System
Regulatory Class: Class II
Product Code: NFJ
Dated: June 7, 2013
Received: June 10, 2013

Dear Ms. Ambrecht:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

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You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, and
Ear, Nose, Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): __K130648__

Device Name: FORUM® Glaucoma Workplace

Indications for Use:

FORUM Glaucoma Workplace is a FORUM software application intended for the management, display, and analysis of visual field data. The FORUM Glaucoma Workplace is indicated as an aid to the detection, measurement, and management of progression of visual field loss.

Prescription Use __x__	AND/OR	Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Ophthalmic, and
Ear, Nose, Throat Devices
510(k) Number: ·/っ., . .